Notice of Allowability	Application No.	Applicant(s)	
	10/617,489	CANTOR, THOMAS L.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *11/28/2006*.

2. ☒ The allowed claim(s) is/are *1-18, 22-39, 58-59, 81-99 now renumbered as claims 1-57*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 11/2/06; 11/28/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *11/21/2006* .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

AMENDMENTS TO THE CLAIMS

1. (currently amended): An isolated antibody that specifically binds to an N-terminal sequence of whole parathyroid hormone (PTH) and is capable of detecting said whole PTH at a physiological level in a mammalian sample, with a proviso that said isolated antibody avoids binding to a ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment.

2. (currently amended): The isolated antibody of claim 1, which is a monoclonal antibody, ~~or~~ a polyclonal antibody or an antibody fragment that specifically binds to whole PTH.

3. (currently amended): The isolated antibody of claim 1, which specifically binds to an epitope comprised in PTH_{1-5}, PTH_{1-6}, PTH_{1-7}, PTH_{1-8}, PTH_{1-9}, PTH_{1-10}, PTH_{1-11}, PTH_{1-12}, PTH_{1-13}, PTH_{1-14}, PTH_{1-15} or PTH_{3-12}.

4. (original): The isolated antibody of claim 1, which specifically binds to the parathyroid hormone peptide human PTH_{1-8}, rat PTH_{1-8}, mouse PTH_{1-8}, bovine PTH_{1-8}, canine PTH_{1-8}, porcine PTH_{1-8}, horse PTH_{1-8}, human PTH_{1-15}, rat PTH_{1-15}, mouse PTH_{1-15}, bovine PTH_{1-15}, canine PTH_{1-15}, porcine PTH_{1-15}, or horse PTH_{1-15}, wherein at least four amino acids in said peptide sequence are part of a reactive portion with the antibody.

5. (currently amended): The isolated antibody of claim 1, which specifically binds to an epitope comprised in ~~PTH_{1-5}, PTH_{1-7}, PTH_{1-8}, PTH_{1-10}, PTH_{1-11}, PTH_{1-13}, PTH_{1-14}, PTH_{1-15}, PTH_{1-16}, PTH_{1-17}, PTH_{1-18}, PTH_{1-19}, PTH_{1-20}, PTH_{1-21}, PTH_{1-22}, PTH_{1-23}, PTH_{1-24}, PTH_{1-25}, PTH_{1-26}, $hPTH_{1-27}$, PTH_{1-28}, PTH_{1-29}, PTH_{1-30}, PTH_{1-31}, PTH_{1-32}, PTH_{1-33}, PTH_{1-34}, PTH_{1-35}, PTH_{1-36}, PTH_{1-37},~~ PTH_{2-5}, PTH_{2-6}, PTH_{2-7}, PTH_{2-8}, PTH_{2-9}, PTH_{2-10}, PTH_{2-11}, PTH_{2-12}, PTH_{2-13}, PTH_{2-14}, or PTH_{2-15}, ~~PTH_{2-16}, PTH_{2-17}, PTH_{2-18}, PTH_{2-19}, PTH_{2-20}, PTH_{2-21}, PTH_{2-22}, PTH_{2-23}, PTH_{2-24}, PTH_{2-25}, PTH_{2-26}, PTH_{2-27}, PTH_{2-28}, PTH_{2-29}, PTH_{2-30}, PTH_{2-31}, PTH_{2-32}, PTH_{2-33}, PTH_{2-34}, PTH_{2-35}, PTH_{2-36}, PTH_{2-37}, PTH_{3-6}, PTH_{3-7}, PTH_{3-8}, PTH_{3-9}, PTH_{3-10}, PTH_{3-11}, PTH_{3-13}, PTH_{3-14}, PTH_{3-15}, PTH_{3-16}, PTH_{3-17}, PTH_{3-18}, PTH_{3-19}, PTH_{3-20}, PTH_{3-21}, PTH_{3-22}, PTH_{3-23}, PTH_{3-24}, PTH_{3-25}, PTH_{3-26}, PTH_{3-27}, PTH_{3-28}, PTH_{3-29}, PTH_{3-30}, PTH_{3-31}, PTH_{3-32}, PTH_{3-33}, PTH_{3-34}, PTH_{3-35}, PTH_{3-36}, PTH_{3-37}, PTH_{4-7}, PTH_{4-8},~~

~~PTH_{4-9}, PTH_{4-10}, PTH_{4-11}, PTH_{4-12}, PTH_{4-13}, PTH_{4-14}, PTH_{4-15}, PTH_{4-16}, PTH_{4-17}, PTH_{4-18}, PTH_{4-19}, PTH_{4-20}, PTH_{4-21}, PTH_{4-22}, PTH_{4-23}, PTH_{4-24}, PTH_{4-25}, PTH_{4-26}, PTH_{4-27}, PTH_{4-28}, PTH_{4-29}, PTH_{4-30}, PTH_{4-31}, PTH_{4-32}, PTH_{4-33}, PTH_{4-34}, PTH_{4-35}, PTH_{4-36}, PTH_{4-37}, PTH_{5-8}, PTH_{5-9}, PTH_{5-10}, PTH_{5-11}, PTH_{5-12}, PTH_{5-13}, PTH_{5-14}, PTH_{5-15}, PTH_{5-16}, PTH_{5-17}, PTH_{5-18}, PTH_{5-19}, PTH_{5-20}, PTH_{5-21}, PTH_{5-22}, PTH_{5-23}, PTH_{5-24}, PTH_{5-25}, PTH_{5-26}, PTH_{5-27}, PTH_{5-28}, PTH_{5-29}, PTH_{5-30}, PTH_{5-31}, PTH_{5-32}, PTH_{5-33}, PTH_{5-34}, PTH_{5-35}, PTH_{5-36}, or PTH_{5-37}.~~

6. (original): The isolated antibody of claim 1, wherein the binding between the antibody and the N-terminal sequence of whole PTH is dependent on the presence of amino acid residues 2-5 of the hPTH.

7. (original): The isolated antibody of claim 1, wherein the binding between the antibody and the N-terminal sequence of whole PTH is dependent on the presence of amino acid residues 3-6 of the hPTH.

8. (currently amended): The isolated antibody or antibody fragment of claim 1, wherein the ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment is a peptide having an amino acid sequence from between PTH_{3-84} and PTH_{34-84}.

9. (currently amended): The isolated antibody of claim 1, wherein the ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment is a peptide having an amino acid sequence of human PTH_{7-84}.

10. (currently amended): A method for measuring a physiological level of whole parathyroid hormone (PTH) in a mammalian sample, which method comprises:

a) obtaining a sample from a mammal to be tested;

b) contacting said sample with an isolated antibody that specifically binds to an N-terminal sequence of whole PTH and is capable of detecting said whole PTH at a physiological level in said mammalian sample, with a proviso that said isolated antibody avoids binding to a ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment in said sample; and

c) assessing a complex formed between said whole ~~parathyroid hormone~~ PTH, if present in said sample, and said antibody, to measure physiological level of said whole ~~parathyroid hormone~~ PTH in said mammalian sample,

wherein said isolated antibody specifically binds to an epitope comprised in PTH_{1-5}, PTH_{1-6}, PTH_{1-7}, PTH_{1-8}, PTH_{1-9}, PTH_{1-10}, PTH_{1-11}, PTH_{1-12}, PTH_{1-13}, PTH_{1-14} or PTH_{1-15}.

11. (original): The method of claim 10, wherein the sample is selected from the group consisting of a serum, a plasma and a blood sample.

12. (original): The method of claim 10, wherein the sample is a clinical sample.

13. (original): The method of claim 10 which is used for clinical management of renal disease subjects, subjects afflicted with osteoporosis or diagnosing primary hyperparathyroidism.

14. (original): The method of claim 10, wherein the mammal is a human.

15. (original): The method of claim 14, wherein the sample is a human clinical sample.

16. (currently amended): The method of claim 10, wherein the antibody is a monoclonal antibody, ~~or~~ a polyclonal antibody or an antibody fragment that specifically binds to whole PTH.

17. (previously presented): The method of claim 10, wherein the antibody specifically binds to an epitope comprised in PTH_{1-6}, PTH_{1-8}, PTH_{1-9}, PTH_{1-12}, or PTH_{1-15}.

18. (currently amended): The method of claim 10, wherein the antibody specifically binds to the ~~parathyroid hormone~~ PTH peptide human PTH_{1-8}, rat PTH_{1-8}, mouse PTH_{1-8}, bovine PTH_{1-8}, canine PTH_{1-8}, porcine PTH_{1-8}, horse PTH_{1-8}, human PTH_{1-15}, rat PTH_{1-15}, mouse PTH_{1-15}, bovine PTH_{1-15}, canine PTH_{1-15}, porcine PTH_{1-15}, or horse PTH_{1-15}, wherein at least four amino acids in said peptide sequence are part of a reactive portion with the antibody.

19–21. (canceled)

22. (currently amended): The method of claim 10, wherein the ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment is selected from the group consisting of PTH_{3-84}, PTH_{4-84}, PTH_{5-84}, PTH_{6-84}, PTH_{7-84}, PTH_{8-84}, PTH_{9-84}, PTH_{10-84}, PTH_{11-84}, PTH_{12-84}, PTH_{13-84}, PTH_{14-84}, PTH_{15-84}, PTH_{16-84}, PTH_{17-84}, PTH_{18-84}, PTH_{19-84}, PTH_{20-84}, PTH_{21-84}, PTH_{22-84}, PTH_{23-84}, PTH_{24-84}, PTH_{25-84}, PTH_{26-84}, PTH_{27-84}, PTH_{28-84}, PTH_{29-84}, PTH_{30-84}, PTH_{31-84}, PTH_{32-84}, PTH_{33-84} and PTH_{34-84}.

23. (currently amended): The method of claim 10, wherein the ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment is a peptide having an amino acid sequence of human PTH_{7-84}.

24. (original): The method of claim 10, wherein the complex is assessed by a sandwich or competitive assay format.

25. (previously presented): The method of claim 24, wherein the antibody that specifically binds to an N-terminal sequence of whole PTH is used as a first antibody in a sandwich format assay, and a second antibody used in the sandwich format assay is an antibody that is capable of binding to a portion of whole PTH other than the N-terminal sequence to which the first antibody binds.

26. (original): The method of claim 25, wherein either the first antibody or the second antibody is attached to a surface and functions as a capture antibody.

27. (previously presented): The method of claim 26, wherein the capture antibody is attached to the surface directly.

28. (original): The method of claim 26, wherein the capture antibody is attached to the surface via a biotin-avidin (or streptavidin) linking pair.

26 29. (original): The method of claim 10, wherein the complex is assessed by a format selected from the group consisting of an enzyme-linked immunosorbent assay (ELISA), immunoblotting, immunoprecipitation, radioimmunoassay (RIA), immunostaining, latex agglutination, indirect hemagglutination assay (IHA), complement fixation, indirect immunofluorescent assay (IFA), nephelometry, flow cytometry assay, plasmon resonance assay, chemiluminescence assay, lateral flow immunoassay, u-capture assay, inhibition assay and avidity assay.

27 30. (previously presented): The method of claim 10, wherein the complex is assessed in a homogeneous assay format.

28 31. (currently amended): The method of claim 10, wherein the physiological level of whole ~~parathyroid hormone~~ PTH is less than 4 pmol/L.

29 32. (currently amended): The method of claim 10, wherein the physiological level of whole ~~parathyroid hormone~~ PTH is from about 0.2 pmol/L to about 4 pmol/L.

30 33. (original): The method of claim 10, which further comprises measuring a PTH peptide fragment level and/or total PTH level.

31 34. (original): The method of claim 33, wherein said sample is contacted with one or more isolated antibodies, and wherein each of said one or more isolated antibodies specifically bind one or more PTH peptide fragments selected from the group consisting of: PTH_{39-84}, PTH_{1-34}, PTH_{43-68}, PTH_{7-84}, PTH_{39-68}, PTH_{53-84}, PTH_{65-84}, PTH_{44-68}, PTH_{19-84}, PTH_{23-84}, PTH_{1-38}, PTH_{1-48}, PTH_{1-58}, PTH_{1-68}, and PTH_{1-78}.

32 35. (original): The method of claim 33, which further comprises comparing at least two parameters selected from the group consisting of the whole PTH level, total PTH peptide fragment level, total PTH level, C-terminal PTH fragment (cPTH) level, N-terminal PTH fragment level, and mid-terminal PTH fragment (mPTH) level.

34 36. (currently amended): The method of claim 35, wherein the results of said comparison are used to determine whether the mammal suffers from a bone turnover related disorder~~, or to monitor bone disease or disorder related treatment~~.

35 37. (previously presented): The method of claim 36, which is used in the diagnosis or monitoring of treatment for adynamic bone disease or severe hyperparathyroidism.

36 38. (original): The method of claim 35, wherein the comparison is in the form of a ratio or proportion between the whole PTH level and the total PTH level.

37 39. (original): The method of claim 35, wherein the comparison is in the form of a ratio or proportion between the whole PTH level versus the combined total of the total PTH level minus the whole PTH level.

40-57. (canceled)

38 58. (original): The method of claim 10, which is used for:

a) differentiating between a person having substantially normal parathyroid function and having hyperparathyroidism;

b) monitoring parathyroid related bone disease and treatment;

c) monitoring effects of therapeutic treatment for hyperparathyroidism; or

d) diagnosing parathyroid related bone disease.

39 59. (currently amended): A kit for measuring a physiological level of whole parathyroid hormone (PTH) in a mammalian sample, which kit comprises, in a container, an isolated antibody that specifically binds to an N-terminal sequence of whole ~~parathyroid hormone (~~PTH~~)~~ and is capable of detecting said whole PTH at a physiological level in a mammalian sample, with a proviso that said isolated antibody avoids binding to a ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment in said sample, wherein said isolated antibody specifically binds to an epitope comprised in PTH_{1-5}, PTH_{1-6}, PTH_{1-7}, PTH_{1-8}, PTH_{1-9}, PTH_{1-10}, PTH_{1-11}, PTH_{1-12}, PTH_{1-13}, PTH_{1-14} or PTH_{1-15}.

60–80. (canceled)

55 81. (currently amended): The method of claim 10, wherein the physiological level of whole ~~parathyroid hormone~~ PTH is from about 7 picogram/ml to about 39 picogram/ml.

56 82. (previously presented): The method of claim 26, wherein the capture antibody is attached to the surface indirectly.

57 83. (previously presented): The method of claim 10, wherein the complex is assessed in a heterogeneous assay format.

58 84. (currently amended): The method of claim 10, wherein the isolated antibody avoids binding greater than about 90% of a ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment in said sample.

59 85. (previously presented): The method of claim 10, wherein the isolated antibody specifically binds to an epitope comprised in PTH_{1-5} or PTH_{1-6}.

60 86. (previously presented): The method of claim 25, wherein one of the first or the second antibody is labeled.

61 87. (currently amended): A method for measuring a physiological level of whole parathyroid hormone (PTH) in a mammalian sample, which method comprises:

a) obtaining a sample from a mammal to be tested;

b) contacting said sample with an isolated antibody that specifically binds to an N-terminal sequence of whole PTH and is capable of detecting said whole PTH at a physiological level in said mammalian sample, with a proviso that said isolated antibody avoids binding to a ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment; and

c) assessing a complex formed between said whole ~~parathyroid hormone~~ PTH, if present in said sample, and said antibody, to measure physiological level of said whole ~~parathyroid hormone~~ PTH in said mammalian sample,

wherein said antibody specifically binds to an epitope comprised in PTH_{1-6}, PTH_{1-8}, PTH_{1-9}, PTH_{1-12}, PTH_{1-15}, or PTH_{3-12}.

46 88. (currently amended): The method of claim 87, wherein the ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment is a peptide having an amino acid sequence of human PTH_{7-84}.

47 89. (currently amended): A method for measuring a physiological level of whole parathyroid hormone (PTH) in a mammalian sample, which method comprises:

a) obtaining a sample from a mammal to be tested;

b) contacting said sample with an isolated antibody that specifically binds to an N-terminal sequence of whole PTH and is capable of detecting said whole PTH at a physiological level in said mammalian sample, with a proviso that said isolated antibody avoids binding to a ~~non-whole~~ a non-(1-84) or non-(1-86) PTH fragment; and

c) assessing a complex formed between said whole ~~parathyroid hormone~~ PTH, if present in said sample, and said antibody, to measure physiological level of said whole ~~parathyroid hormone~~ PTH in said mammalian sample,

wherein said antibody specifically binds to the ~~parathyroid hormone~~ PTH peptide human PTH_{1-8}, rat PTH_{1-8}, mouse PTH_{1-8}, bovine PTH_{1-8}, canine PTH_{1-8}, porcine PTH_{1-8}, horse PTH_{1-8}, human PTH_{1-15}, rat PTH_{1-15}, mouse PTH_{1-15}, bovine PTH_{1-15}, canine PTH_{1-15}, porcine PTH_{1-15}, or horse PTH_{1-15}, wherein at least four amino acids in said peptide sequence are part of a reactive portion with the antibody.

48 90. (currently amended): The method of claim 89, wherein the ~~non-whole~~ non-(1-84) or non-(1-86) PTH fragment is a peptide having an amino acid sequence of human PTH_{7-84}.

49 91. (currently amended): The method of claim 10, wherein the isolated antibody that specifically binds to an N-terminal sequence of whole PTH is produced by immunizing a mammal

with whole PTH, collecting the antibody from the mammal and isolating the antibody by binding the antibody to an epitope comprised in PTH_{1-5}, PTH_{1-6}, PTH_{1-7}, PTH_{1-8}, PTH_{1-9}, PTH_{1-10}, PTH_{1-11}, PTH_{1-12}, PTH_{1-13}, PTH_{1-14} or PTH_{1-15}, and the isolated antibody specifically binds to whole PTH.

92. (previously presented): The method of claim 91, wherein the mammal is a goat.

93. (previously presented): The method of claim 91, wherein the whole PTH is human whole PTH and the peptide is a human or rat PTH peptide.

94. (previously presented): The method of claim 91, wherein the whole PTH is rat whole PTH and the peptide is a human or rat PTH peptide.

95. (previously presented): The method of claim 10, wherein the mammal is a rat.

96. (currently amended): The method of claim 10, wherein the isolated antibody that specifically binds to an N-terminal sequence of whole PTH is produced by immunizing a mammal with whole PTH, collecting the antibody from the mammal and isolating the antibody using a peptide selected from the group consisting of PTH_{1-5}, PTH_{1-6}, PTH_{1-7}, PTH_{1-8}, PTH_{1-9}, PTH_{1-10}, PTH_{1-11}, PTH_{1-12}, PTH_{1-13}, PTH_{1-14} and PTH_{1-15}, and the isolated antibody specifically binds to whole PTH.

97. (new): The method of claim 35, wherein the results of said comparison are used to monitor bone disease or disorder related treatment.

98. (new): The isolated antibody or antibody fragment of claim 8, wherein the non-(1-84) or non-(1-86) PTH fragment is selected from the group consisting of PTH_{4-84}, PTH_{5-84}, PTH_{6-84}, PTH_{7-84}, PTH_{8-84}, PTH_{9-84}, PTH_{10-84}, PTH_{11-84}, PTH_{12-84}, PTH_{13-84}, PTH_{14-84} and PTH_{15-84}.

99. (new): The method of claim 22, wherein the non-(1-84) or non-(1-86) PTH fragment is selected from the group consisting of PTH_{4-84}, PTH_{5-84}, PTH_{6-84}, PTH_{7-84}, PTH_{8-84}, PTH_{9-84}, PTH_{10-84}, PTH_{11-84}, PTH_{12-84}, PTH_{13-84}, PTH_{14-84} and PTH_{15-84}.

REMARKS

Claims 1-83 were previously submitted for examination. Claims 1-9 and 60-80 were previously withdrawn from consideration due to a restriction requirement, claims 19-21 and 40-57 were previously canceled, and claims 81-96 were previously added. In the November 21, 2006 telephonic interview, the Examiner indicated that the restriction requirement on claims 1-9 is withdrawn. Claims 60-80 have been cancelled, claims 1-3, 5, 8-10, 16, 18, 22, 23, 31, 32, 36, 59, 81, 84, 87-91 and 96 have amended and claims 97-99 have been added by the present amendment. Therefore, claims 1-18, 22-39, 58, 59 and 81-99 are currently under consideration.

The phrase "non-whole PTH fragment" in claims 1, 8-10, 22, 23, 59, 84 and 87-90 have been replaced with "non-(1-84) or non-(1-86) PTH fragment." Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in paragraph **[0055]** of the present specification which states that "whole parathyroid hormone (PTH)" or "wPTH" refers to the complete molecule of PTH, and in paragraphs **[0099]** to **[00105]** of the present specification which show that the complete molecules of PTH from various mammalian species have 84 or 86 amino acid residues. Therefore, "non-whole PTH fragment" is synonymous with "non-(1-84) or non-(1-86) PTH fragment" and this amendment does not change the scope of the amended claims. Additional support for reciting "non-(1-84) PTH fragment" can be found in paragraphs **[0004]**, **[0007]**, **[0047]**, **[0049]**, **[00145]**, **[00147]**, **[00159]**, **[00160]**, and Figures 18 and 20.

Claims 2 and 16 have been amended to clarify that the recited monoclonal antibody, polyclonal antibody or antibody fragment specifically binds to whole PTH. Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in paragraph **[0071]** of the present specification which states that the term "specifically binds" refers to the specificity of an antibody such that it preferentially binds to a defined target. In addition, as shown in paragraphs **[0040]**, **[0043]**, **[00132]** and **[00154]**, and in Figures 11 and 14, an exemplary antibody preferentially binds to whole PTH in the presence of a large excess amount of an exemplary "non-(1-84) PTH fragment," PTH (7-84) fragment. These data show that the exemplary antibody specifically binds to whole PTH.

Claim 3 has been amended to add certain PTH epitopes that have been deleted from the original claim 5. Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in original claim 5.

Claim 5 has been amended to delete certain PTH epitopes from the original claim 5.

Claims 10, 18, 31, 32, 59, 81, 87 and 89 have been amended to recite the abbreviated name "PTH" instead of the full name "parathyroid hormone" for consistency.

Claim 36 has been amended to delete "to monitor bone disease or disorder related treatment" and new claim 97 has been added to recite "to monitor bone disease or disorder related treatment." Both amended claim 36 and the new claim 97 find support throughout the present application as originally filed and, *inter alia*, in original claim 36.

Claims 91 and 96 have been amended to recite that the isolated antibody specifically binds to whole PTH. Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in paragraph **[0071]** of the present specification which states that the term "specifically binds" refers to the specificity of an antibody such that it preferentially binds to a defined target. In addition, as shown in paragraphs **[0040]**, **[0043]**, **[00132]** and **[00154]**, and in Figures 11 and 14, an exemplary antibody preferentially binds to whole PTH in the presence of a large excess amount of an exemplary "non-(1-84) PTH fragment," PTH (7-84) fragment. These data show that the exemplary antibody specifically binds to whole PTH.

New claim 98 depends on claim 8 and recites a subset of PTH epitopes recited in claim 8. New claim 98 finds support throughout the present application as originally filed and, *inter alia*, in original claim 8.

New claim 99 depends on claim 22 and recites a subset of PTH epitopes recited in claim 22. New claim 98 finds support throughout the present application as originally filed and, *inter alia*, in original claim 22.

Accordingly, the present amendments do not introduce any new matter into the present application.

Applicant's Statements of the Substances of the November 7, 2006 Interview

On November 7, 2006, Examiners Jacob Cheu, Long Le, Larry Helms, Inventor Thomas L. Cantor and the undersigned had an interview to discuss the various outstanding issues for the present application. Applicant and the undersigned greatly appreciate Examiners' granting the interview and discussing the various issues with Inventor Thomas L. Cantor and the undersigned. The following is a summary of the November 7, 2006 interview:

- Applicant presented experimental data to distinguish Colford et al. reference, particularly the experimental data indicating the difference between the antibodies in the instant invention and that of the Colford et al. with respect to the binding of the non-whole PTH fragment in the respective PTH assay.

- Applicant further distinguished the teachings of Rucinski et al. from the instant invention, particularly the fact that Rucinski et al do not teach the use of an antibody that avoids binding to a non-whole PTH fragment.

Applicant's Statements of the Substances of the November 21, 2006 Interview

On November 21, 2006, Examiners Jacob Cheu and the undersigned had a telephonic interview to discuss the various outstanding issues for the present application. Applicant and the undersigned greatly appreciate Examiners' granting the interview and discussing the various issues with the undersigned. The following is a summary of the November 21, 2006 interview and applicant's response to the Examiner's requests raised in the interview:

- The Examiner indicated that in order to place the present application into condition for allowance, terminal disclaimers as related to the two parent patents,

U.S. Patent Nos. 6,689,566 and 6,743,590, are required. Applicant filed the requested terminal disclaimers on November 21, 2006.

- The Examiner indicated that the restriction requirement on claims 1-9 is withdrawn. Applicant appreciates the withdraw and has changed the status of claims 1-9 accordingly.

- The Examiner requested the cancellation of claims 60-80. Applicant has changed the status of claims 60-80 accordingly.

- The Examiner requested the replacement of "non-whole PTH fragment" with "non-(1-84) or non-(1-86) PTH fragment" in various claims. Applicant has made such an amendment in claims 1, 8-10, 22, 23, 59, 84 and 87-90.

- The Examiner requested further clarification of the "antibody fragment" in claims 2 and 16. Claims 2 and 16 have been amended to clarify that the recited monoclonal antibody, polyclonal antibody or antibody fragment specifically binds to whole PTH.

- The Examiner requested the cancellation of claim 5. Applicant has placed certain PTH epitopes recited in claim 5 into the presently pending claim 3, kept a subset of PTH epitopes in the presently pending claim 5, and has deleted a majority of PTH epitopes recited previously.

- The Examiner requested that, to be consistent, abbreviated name "PTH" be used in certain places instead of the full name "parathyroid hormone." Applicant has amended claims 10, 18, 31, 32, 59, 81, 87 and 89 to recite the abbreviated name "PTH" instead of the full name "parathyroid hormone."

- The Examiner requested that claim 36 be separated into two claims. Applicant has deleted "to monitor bone disease or disorder related treatment" in presently

pending claim 36 and has added new claim 97 to recite "to monitor bone disease or disorder related treatment."

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CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 53221-2000623. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 28, 2006

Respectfully submitted,

By _____

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Sir:

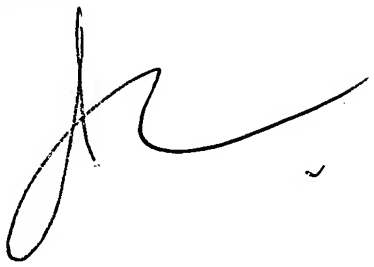
As discussed in the patentability conference, applicant amended the claim language as suggested by us.

With respect to claim 1, the non-(1-86) is from horse PTH (SEQ ID No. 7).

With respect to claim language non-(1-84), this language is consistent with the reexam case.

Importantly, reexam case has also been allowed after the interview.

Jacob



P.S: TD has filed and approved.